Form PTO-1390 (REV 10-97)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: 19601-000120US

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 09/600348

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US99/00835	13 January 1999	14 January 1998

TITLE OF INVENTION

EXTENDIBLE STENT APPARATUS

APPLICANT(S) FOR DO/EO/US

VARDI, GIL M. et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.

2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.

3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).

4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States receiving Office (RO/US)

6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).

7. ☐ Amendments as to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.

8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. ☒ An unexecuted oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).

10. ☐ A translation of the annexes to the International Preliminary examination Report under PCT Article 36 (35 U.S.C. 371(c)(5))

Items 11. to 16. below, concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98.

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.

13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.

14. ☐ A substitute specification.

15. ☐ A change of power of attorney and/or address letter.

16. ☒ Other items or information: (1) Written Opinion (2) Examination Report and (3) Search Report

U.S. APPLICATION NO. (if known, see 37 C.F.R 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
09/600348	PCT/US99/00835	19601-000120US

17. ☒ The following fees are submitted:	CALCULATIONS PTO USE ONLY
BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5)):	
Search Report has been prepared by the EPO or JPO 840.00	
International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) 670.00	
No international preliminary examination fee paid to USPTO (37 C.F.R. 1.482) but international search fee paid to USPTO (37 C.F.R. 1.445(a)(2) 760.00	
Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2) paid to USPTO 970.00	
International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) 96.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 670.00
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 130.00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total Claims	33-20=	13	x $18.00	$ 234.00
Independent Claims	7-3=	4	x $7800	$ 312
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $260.00	$
TOTAL OF ABOVE CALCULATIONS =				$
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 C.F.R. 1.9, 1.27, 1.28).				$
SUBTOTAL =				$
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 C.F.R. 1.492(f)). +				$
TOTAL NATIONAL FEE =				$
Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). $40.00 per property +				$
TOTAL FEES ENCLOSED =				$
			Amount to be refunded:	$
			charged	$1346.00

a. ☐ A check in the amount of $_____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. 20-1430 in the amount of **$ 1346.00** to cover the above fees.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 20-1430. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO
Roger T. Barrett
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SIGNATURE

Roger T. Barrett
NAME

41,599
REGISTRATION NUMBER

PATENT

"Express Mail" Label No. EK435478485US
Date of Deposit July 14, 2000

Attorney Docket No.: 19601-000120

I hereby certify that this is being deposited with the United States Postal Service "Express Mail Post Office to Address" service under 37 CFR 1.10 on the date indicated above and is addressed to:

BOX PCT
Assistant Commissioner for Patents
Washington, D.C. 20231

By: Sara B. McPeak

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Gil M. Vardi, et al.

Filed: Herewith

For: EXTENDIBLE STENT APPARATUS

Intnl. Appl. No.: PCT/US99/00835

Intnl. Filing Date: 13 January 1999

Priority Filing Date: 14 January 1998

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-referenced application, please enter the following amendments and remarks.

IN THE CLAIMS:

Please amend the claims as follows (all claims are set forth for convenient reference):

1. (As filed) A stent for placement in a bifurcated body lumen having a main branch and a side branch, said stent comprising:

a main tubular stent body having a first end, a second end, a lumen therethrough, and a side opening have a plurality of laterally deployable elements therein.

Please cancel claims 2-21.

Please add the following claims:

--22. A stent for placement in a bifurcated body lumen having a main branch and a side branch, said stent comprising:

a main tubular stent body having a proximal end, a distal end, a lumen therethrough, and at least one side opening located between the proximal end and the distal end, said side opening having a plurality of laterally deployable elements disposed about said side opening.

23. A stent as in claim 22 wherein the laterally deployable elements are formed as an integral part of the stent body.

24. A stent as in claim 22 wherein, prior to expansion, the laterally deployable elements are aligned in a tubular envelope defined by the tubular stent body.

25. A stent as in claim 22 wherein, upon expansion, the laterally deployable elements extend outwardly from the tubular stent body.

26. A stent as in claim 22 wherein the main tubular stent body is deformable to permit expansion by a balloon catheter.

27. A stent as in claim 22 wherein the main tubular stent body is fabricated using materials with self-expanding characteristics.

28. A stent as in claim 22 wherein at least a portion of the main stent body is radiopaque.

29. A stent as in claim 22 wherein at least a portion of the main stent body surrounding the side opening is radiopaque.

30. A stent as in claim 22 wherein the side opening comprises a continuous band.

31. A stent as in claim 30 wherein the laterally deployable elements are inwardly projecting loops of the continuous band.

32. A stent as in claim 22 wherein the side opening is a generally circular side opening.

33. A stent for placement in a bifurcated body lumen having a main branch and a side branch, said stent comprising:

a main tubular stent body having a proximal end, a distal end, a lumen therethrough, at least one side opening located between the proximal end and the distal end, and a spine region along a longitudinal axis of the stent body, said spine region having a first axial spine in a proximal portion of said stent and a second axial spine in a distal portion of said stent, said first axial spine having a different strut pattern than said second axial spine.

34. A stent as in claim 33 wherein the first axial spine expands radially in response to a first radially outward force, and the second axial spine expands radially in response to a second radially outward force, wherein the first force is less than the second force.

35. A stent as in claim 33 wherein the first axial spine expands radially in response to a first radially outward force, and the second axial spine expands radially in response to a second radially outward force, wherein the first force is greater than the second force.

36. A stent system comprising:

a first stent, said first stent comprising a main tubular stent body having a proximal end, a distal end, a lumen therethrough, and at least one side opening located between the proximal end and the distal end, said side opening having a plurality of laterally deployable elements disposed about said side opening; and

a second stent adapted to fit within and contact the laterally deployable elements of the main tubular stent body.

37. A method for deploying a stent, said method comprising:

expanding a main tubular stent body; and

laterally deflecting a plurality of elements disposed about a side opening on the main tubular stent body.

38. A method as in claim 37 wherein expanding said main tubular stent body comprises expanding said main tubular stent body so that said side opening on the stent body is aligned with a branching body lumen.

39. A method as in claim 37 further comprising placing a second stent into the side opening so that said second stent engages the laterally deflected elements.

40. A method for deploying a stent in a bifurcated lumen, said method comprising:

providing a stent having a first portion, a second portion and a side opening between said portions;

expanding said first portion against a luminal wall segment on one side of the bifurcation;

aligning the side opening with the branch lumen; and

expanding the second portion on the other side of the bifurcation.

41. The method of claim 40 wherein said first portion has a first axial spine and said second portion has a second axial spine.

42. The method of claim 41 wherein said first axial spine comprises a different strut pattern than said second axial spine.

43. The method of claim 41 wherein said first and second axial spines are adapted to expand radially at different radially outward forces.

44. A stent for placement in a bifurcated body lumen having a main branch and a side branch, said stent comprising:

a radially expandable stent body having a proximal end, a distal end, a lumen therethrough, and an expandable side opening, said side opening having a perimeter defined by a continuous band of material.

45. A stent as in claim 44 wherein said expandable side opening is generally circular in shape prior to expansion of said stent body and generally circular in shape after expansion of said stent body.

46. A stent as in claim 44 wherein said expandable side opening is generally elliptical or oval in shape prior to expansion of said sent body and is generally circular in shape after expansion of said stent body.

47. A stent as in claim 44 wherein said continuous band of material comprises protrusions which project inwardly to define a peripheral edge of the side opening.

48. A stent as in claim 44 wherein said expandable side opening is symmetric about a longitudinal axis of said stent body.

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49. A stent as in claim 44 wherein said expandable side opening is symmetric about an axis extending laterally across said stent body.

50. A stent as in claim 44 wherein a shape of said side opening prior to expansion of said stent body is generally the same as said side opening shape after expansion of said stent body.

51. A stent as in claim 44 wherein a shape of said side opening remains generally constant during radial expansion of said stent body.

52. A stent as in claim 44 wherein an area of said side opening remains generally constant during expansion of said stent body.

53. A stent as in claim 44, wherein said side opening is adapted to expand when said stent body is radially expanded, and said side opening is adapted to further expand generally independent of said stent body radial expansion.--

REMARKS

Claims 2-21 have been canceled and claims 22-53 have been added. Examination of the claims, as amended, is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

Roger T. Barrett
Reg. No. 41,599

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VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27(c)) - SMALL BUSINESS CONCERN

Applicant or Patentee: Gil M. Vardi, Charles J Davidson, Eric Elam and Stuart Lin
Application or Patent No.: 09/600348
Filed or Issued: July 14, 2000
Title: EXTENDIBLE STENT APPARATUS

I hereby declare that I am:

[ ] the owner of the small business concern identified below:
[X] an official of the small business concern empowered to act on behalf of the concern identified below.

Name of Small Business Concern: ADVANCED STENT TECHNOLOGIES, INC.
Address of Small Business Concern: 7026 Koll Center Parkway
Pleasanton, CA 94566

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention, entitled EXTENDIBLE STENT APPARATUS by inventor(s) Gil M. Vardi, Charles J Davidson, Eric Elam and Stuart Lin described in:

[ ] the specification filed herewith;
[X] Application No. 09/600348, filed July 14, 2000;
[ ] Patent No _____, issued _____.

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

*NOTE Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27)

Name: _____
Address: _____
_____

[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

Name: _____
Address: _____
_____

[ ] Individual [ ] Small Business Concern [ ] Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Person Signing: Niyazi U. Beyhan
Title of Person if Other than Owner: President and COO
Address of Person Signing 7026 Koll Center Parkway
Pleasanton, CA 94566

Signature _____ Date 11/2/2000

DE 7025207 v1

EXTENDIBLE STENT APPARATUS

BACKGROUND OF THE INVENTION

A type of endoprosthesis device, commonly referred to as a stent, may be placed or implanted within a vein, artery or other tubular body organ for treating occlusions, stenoses, or aneurysms of a vessel by reinforcing the wall of the vessel or by expanding the vessel. Stents have been used to treat dissections in blood vessel walls caused by balloon angioplasty of the coronary arteries as well as peripheral arteries and to improve angioplasty results by preventing elastic recoil and remodeling of the vessel wall. Two randomized multicenter trials have recently shown a lower restenosis rate in stent treated coronary arteries compared with balloon angioplasty alone (Serruys, PW et al. New England Journal of Medicine 331: 489-495, 1994, Fischman, DL et al. New England Journal of Medicine 331: 496-501, 1994). Stents have been successfully implanted in the urinary tract, the bile duct, the esophagus and the tracheo-bronchial tree to reinforce those body organs, as well as implanted into the neurovascular, peripheral vascular, coronary, cardiac, and renal systems, among others. The term "stent" as used in this Application is a device which is intraluminally implanted within bodily vessels to reinforce collapsing, dissected, partially occluded, weakened, diseased or abnormally dilated or small segments of a vessel wall.

One of the drawbacks of conventional stents is that they are generally produced in a straight tubular configuration. The use of such stents to treat diseased vessels at or near a bifurcation (branch point) of a vessel may create a risk of compromising the degree of patency of the primary vessel and/or its branches, or the bifurcation point and also limits the ability to insert a second stent into the side branch if the result of treatment of the primary, or main, vessel is suboptimal. Suboptimal results may occur as a result of several mechanisms, such as displacing diseased tissue, plaque shifting, vessel spasm, dissection with or without intimal flaps, thrombosis, and embolism.

The risk of branch compromise is increased generally in two anatomical situations. First, a side branch may be compromised when there is a stenosis in the origin

of the side branch. Second, when there is an eccentric lesion at the bifurcation site, asymmetric expansion can cause either plaque shifting or dissection at the side branch origin. There are reports of attempts to solve this problem by inserting a balloon into the side branch through the struts of a stent deployed in the main branch spanning the bifurcation point; however, this technique carries the risk of balloon entrapment and other major complications (Nakamura, S. et al., Catheterization and Cardiovascular Diagnosis 34: 353-361 (1995)). Moreover, adequate dilation of the side branch is limited by elastic recoil of the origin of the side branch. In addition, insertion of a traditional stent into a main vessel spanning a the bifurcation point may pose a limitation to blood flow and access to the side branch vessel. The term "stent jail" is often used to describe this concept. In this regard, the tubular slotted hinged design of the Palmaz-Schatz intracoronary stent, in particular, is felt to be unfavorable for lesions with a large side branch and is generally believed to pose a higher risk of side branch vessel entrapment where the stent prevents or limits access to the side branch. Id.

One common procedure for intraluminally implanting a stent is to first open the relevant region of the vessel with a balloon catheter and then place the stent in a position that bridges the treated portion of the vessel in order to prevent elastic recoil and restenosis of that segment. The angioplasty of the bifurcation lesion has traditionally been performed using the "kissing" balloon technique where two guidewires and two balloons are inserted, one into the main branch and the other into the side branch. Stent placement in this situation requires the removal of the guidewire from the side branch and reinsertion through the stent struts, followed by the insertion of a balloon through the struts of the stent along the guidewire. The first removal of the guidewire poses the risk of occlusion of the side branch during the deployment of the stent in the main branch.

In general, when treating a bifurcation lesion using commercially available stents, it is important to cover the origin of the branch because if left uncovered, this area is prone to restenosis. In order to cover the branch origin, conventional stents inserted into the branch must protrude into the lumen of the main artery or vessel from the branch (which may cause thrombosis, again compromising blood flow). Another frequent complication experienced when stenting bifurcated vessels is the narrowing or occlusion of the origin of a side branch spanned by a stent placed in the main branch. Additionally, placement of a stent into a main vessel where the stent partially or completely extends across the opening of a branch makes future access into such branch vessels difficult if

not impossible. As a result, conventional stents are often placed into the branch close to the origin, but generally not covering the origin of the bifurcation.

Lastly, conventional stents are difficult to visualize during and after deployment, and in general are not readily imaged by using low-cost and easy methods such as x-ray or ultrasound imaging. While some prior art balloon catheters (and not stents) are "marked" at the proximal and distal ends of the balloon with imageable patches, few stents are currently available which are marked with or which are at least partly constructed of, a material which is imageable by currently known imaging procedures commonly used when inserting the stents into a vessel, such as ultrasound or x-ray imaging. The invention described in this Application would not work with endoscopy as currently used as an imaging method due to size limitations, but future advances in limiting the size of endoscopic imaging devices may in the future make endoscopic imaging compatible with the stents of the invention.

Accordingly, there is a need for improved stent apparatuses, most particularly for applications within the cardiac, coronary, renal, peripheral vascular, gastrointestinal, pulmonary, urinary and neurovascular systems and the brain which 1) completely covers the bifurcation point of bifurcation vessels; 2) may be used to treat lesions in one branch of a bifurcation while preserving access to the other branch for future treatment; 3) allows for differential sizing of the stents in a bifurcated stent apparatus even after the main stent is implanted; 4) may be delivered intraluminally by catheter; 5) may be used to treat bifurcation lesions in a bifurcated vessel where the branch vessel extends from the side of the main vessel; and 6) is marked with, or at least partly constructed of, material which is imageable by commonly used intraluminal catheterization visualization techniques including but not limited to ultrasound or x-ray.

SUMMARY OF THE INVENTION

The present invention concerns novel stent apparatuses for methods, and kits use in treating lesions at or near the bifurcation point in bifurcated vessels. More particularly, the invention concerns a stent apparatus with a main tubular stent body having at least one side opening which may further comprise an extendable or second stent inserted through the side opening and at least partly in registry with the wall of the side opening.

As used herein, the term "vessel" means any body lumen or tubular tissue within the cardiac, coronary, renal, peripheral vascular, gastrointestinal, pulmonary, urinary and neurovascular systems and the brain. Devices constructed in accordance with the invention include, singularly or in combination, a main expandable tubular stent body having at least one side opening (usually substantially circular) located between its proximal and distal end openings, which side opening may further comprise a radially expandable portion extending laterally outward from the edges of the side opening; and an expandable branch second stent comprising proximal and distal end openings and which may further comprise a contacting portion at its proximal end, and which may be constructed to form an angularly variable branched stent apparatus when inserted through a side opening of the main stent. The radially expandable portion preferably comprises a plurality of laterally deployable elements, such as loops, tabs, beams, or the like, attached or coupled to a peripheral edge of the side opening. Usually, the elements will project inwardly from the periphery into the side hole so that they may be deployed radially outwardly from the periphery to open in a petal-like fashion. The elements may be formed integrally as part of the tubular body structure, e.g., being formed from the bent wire or band or from the cut tubular structure which defines the stent structure. Alternatively, they could be formed separately and subsequently attached by crimping, welding, folding, interference fitting, etc. Optionally, the expandable portion may be covered with a fabric or the entire stent structure membrane to help form the transition between the main body lumen and the lumen of the second stent. The stents of the invention are marked with, or at least partially constructed of, a material which is imageable during intraluminal catheterization techniques, most preferably but not limited to ultrasound and x-ray, preferably being radiopaque.

In a preferred aspect of the stent design, the side hole will be defined by a continuous band or pattern of material which defines the periphery of the side hole. The band may have a circular, oval, or other regular geometry in which case the width and area of the side hole will remain generally constant as the stent is expanded. Alternatively, the continuous band may comprise discontinuities over its length so that the area and/or width of the side hole may expand together with the stent structure. Preferably, the continuous band will include inwardly projecting loops, fingers, or other protrusions which will define the laterally deployable elements which project inwardly from the peripheral edge of the side opening. The inwardly projecting loops or other

elements may be overlapping or non-overlapping. The use of overlapping looped structures maximizes the length of the inwardly projecting elements after they are unfolded and opened inwardly into the side branch, as described in more detail below.

In another aspect of the present invention, a stent for placement in a bifurcated body lumen comprises a main tubular body having a first end, a second end, and a side opening therebetween. A first portion of the main tubular body between the first end and the side hole opens in response to a first radially outward pressure, typically provided by an expansion balloon. A second portion of the main tubular body between the side hole and the second end opens in response to a second pressure, again typically applied by an expansion balloon. By constructing the main tubular body so that the first opening pressure is less than the second opening pressure, the stent can have differential opening characteristics. That is, by introducing a balloon expansion catheter into the stent and applying a constant pressure over the entire length of the balloon, the first portion of the stent will yield and open before the second portion of the stent. The particular embodiments described below, the first yield pressure will typically be in the range from 1 atmospheres to 10 atmospheres while the second yield pressure will typically be in the range from 2 atmospheres to 18 atmospheres. Such stent structures may be placed by initially opening and deploying the first portion, typically the proximal portion on the same side of the bifurcation as the deployment catheter, and thereafter positioning the side hole to align more precisely with the bifurcated secondary blood vessel. After the proper positioning has been achieved, the second stent portion can then be opened, conveniently using the same expansion balloon which has been inflated to a higher inflation pressure. Such stents will typically include the laterally deployable elements disposed around the side opening, as described above, and will optionally be used in combination with secondary stents, as described above.

The stent structures as described previously may combine conventional stent elements, such as serpentine rings, diamond or box structures, axial expansion members, and the like. In addition, in order to provide the differential expansion characteristics, the main tubular bodies of the stents may include axial spine structures which differ from the remaining portions of the tubular body of the stent. For example, the first portion of the stent may have an axial spine which readily expands circumferentially. By then providing a spine section on the second portion of the stent which is more resistant to circumferential expansion, the desired differential expansion

will be achieved. Alternatively, the differential expansion can be achieved by employing stent patterns which are uniformly easier or more difficult to radially expand over their entire peripheral length. Specific examples of both structures will be described below.

The stent apparatuses of the invention offers significant and novel advantages over prior art stents in that the stents of the invention 1) can completely cover the bifurcation point of a branched vessel; 2) can accommodate main and branch stents of differing sizes, thus providing a better fit where the main and branch vessels are of different sizes or where the main and branch vessels are occluded to different degrees; 3) can fit branched vessels where the branch extends laterally from the side of the main vessel; 4) may be used to treat lesions in one branch of a bifurcation while preserving complete access to the other branch for future treatment; 5) may be delivered intraluminally by catheter; and 6) are marked with, or at least partly constructed of, material which is imageable by commonly used intraluminal catheterization visualization techniques including but not limited to ultrasound or x-ray, but not endoscopy.

Thus, it is an object of the present invention to provide both a double-stent apparatus and a single-stent apparatus, each of which may be used to cover the origin of a bifurcation in a branched vessel.

Another object of the invention is to provide a single-stent apparatus which may be used to treat only one branch of a bifurcation lesion while leaving access to the second branch unobstructed.

Additionally, it is an object of the invention to provide a stent apparatus which is itself imageable by methods commonly used during catheterization such as x-ray or ultrasound.

Yet another object of the invention is to provide a bifurcating double-stent device wherein the main stent and the branch stent or stents may be of different sizes.

Lastly, it is an important object of the invention to provide a stent apparatus which may be used to treat bifurcated vessels where the vessel bifurcation extends laterally from the side of the main vessel.

These objects and other object advantages and features of the invention will become better understood from the detailed description of the invention and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic depiction of the double-stent apparatus of the present invention in which both the main stent and the branch stent are fully dilated.

Fig. 2 is a schematic depiction of the main stent of the apparatus of the invention as deployed, with the side opening in registry with a vessel bifurcation point.

Fig. 3 is a schematic depiction of the branch stent of the apparatus as deployed, with the contacting portion fully expanded to contact the origin of the bifurcated vessel.

Fig. 4 is a schematic depiction of the main stent of the apparatus deployed within a subject vessel, after inflation of a balloon to expand the main stent to fit the walls of the subject vessel.

Fig. 5 is a schematic depiction of the double-stent bifurcating stent apparatus, where the main stent is deployed and showing the placement of the branch stent apparatus prior to full deployment of the branch stent.

Fig. 6a depicts initial placement of the main stent of the bifurcating stent apparatus into the vessel, along with the insertion of a guidewire and stabilizing catheter for placement of the branch stent into the branch vessel of the subject.

Fig. 6b is a schematic depiction showing the main stent of the invention expanded by balloon expansion.

Fig. 6c is a schematic depiction of the deployment of the branch stent over the side branch guidewire, through one of the side openings in the main stent and into the branch vessel of the subject.

Fig. 6d is a schematic depiction of the removal of the protective sheath of the branch stent allowing for full expansion of the contacting portion prior to final placement and deployment.

Fig. 6e is a schematic depiction of the compressed branch stent positioned into the branch by the catheter with the contacting portion at least partly contacting the side opening in the main stent, but prior to full expansion of the branch stent.

Fig. 6f is a schematic depiction of the fully expanded main stent and the fully positioned and expanded branch stent, where the branch stent is being dilated by inflation of a balloon.

Fig. 6g is a schematic depiction of the fully expanded bifurcating double stent of the invention, positioned into the bifurcation point in a subject vessel.

Fig. 7 is a schematic depiction of the main stent with optional expandable portion, prior to balloon expansion of the expandable portion.

Fig. 8 is a schematic depiction of balloon expansion of the optional expandable portion of the main stent to cover a vessel bifurcation point.

Fig. 9 is a schematic depiction of the main stent with the optional expandable portion fully expanded to extend laterally from the side opening of the main stent.

Fig. 10 illustrates a first stent pattern having a side hole and differential expansion characteristics in a "rolled out" view.

Fig. 11 illustrates a second stent pattern having a side hole and differential expansion characteristics in a "rolled out" view.

Fig. 12 illustrates a third stent pattern having a side hole and differential expansion characteristics in a "rolled out" view.

Figs. 13A-13H illustrate the deployment of any one of the stents of Figs. 10-12 in a bifurcated blood vessel or a secondary stent is placed through the side hole of the main stent.

The rectilinear matrices shown in the drawings are intended to show the shapes of the surfaces only, and do not illustrate the actual surface patterns or appearances of the stent apparatuses of the invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The bifurcating double-stent apparatus 10 of the present invention comprises a generally cylindrical main stent 12 and a generally cylindrical branch stent 15, which are shown as fully dilated in a subject main vessel 8 and a subject branch vessel 7, as illustrated in Fig. 1.

The main stent 12 contains at least one generally circular side opening 16 located between the proximal end 26 and the distal end 28 of the main stent 12 (Fig. 2), which opening is positioned over and in registry with the opening 48 of a branch vessel in a vessel bifurcation 50, as shown in Fig. 2. The stent 12 and the side opening are imaged during imaging procedures either by constructing the stent of imageable materials or by placing markers 56 at appropriate locations, such as around the perimeter of the side opening 16 in the main stent 12, and at the proximal end 26 and distal end 28 of the main stent, as illustrated in Fig. 4.

As shown in the embodiment of the invention illustrated in Fig. 4, a guidewire 20 is inserted into the vessel 8 prior to insertion of the main stent 12, and is used to guide the main stent 12 into position within the vessel 8. Prior to insertion and expansion, the main stent 12 is disposed around the distal end of a catheter 48 which may include an inflatable balloon 24. The main stent/catheter apparatus is then threaded onto the main guidewire 20 and into the vessel 8. The main stent 12 is radially expanded by inflation of the balloon 24 until it expands the walls of the vessel 8, and is thus affixed into place.

In a second embodiment of the invention, the branch stent apparatus 15 of the present invention comprises a generally cylindrical stent comprising a proximal end 30 and a distal end 32, as shown in Fig. 3. The proximal end 30 comprises a contacting portion. illustrated here as extended loops 18, which contacting portion, when expanded, is positioned within the lumen 58 of the main vessel 8 (Fig. 3) and at least partially contacting the perimeter of the side opening 16 of the main stent 12. Fig. 4 illustrates the positioning of the main stent 12 (without optional contacting portion) in the main vessel 8 as fully expanded by inflation of the balloon 24.

As shown in the embodiments illustrated in Figs. 4, 5 and 7, the ends of the main stent 12 and the expandable branch stent 15 and the contacting portion 18 are visible during insertion by placing imageable markers 56 around the ends of the main 12 and branch 15 stents and the contacting portion 18 and at the proximal end 30 and distal end 32 of the branch stent. Alternatively, the stent may be at least partially constructed of material which is imageable by methods including but not limited to ultrasound or x-ray imaging (but not endoscopic imaging).

As shown in yet another embodiment, the stents of the invention are combined to form a bifurcating double stent as illustrated in Figs. 5 and 6a-g. After insertion of the main stent as described above but prior to expansion of the main stent (Fig. 6a), the branch stent 15 is inserted through a side opening 16 of the main stent 12, a guidewire 36 and a stabilizing catheter 44 are inserted through the side opening 16 in the main stent 12, and into a branch vessel 7 (Fig. 6a). The stabilizing catheter 44 is used to place the side opening 16 in the main stent 12 over the bifurcation point 50 in the bifurcated vessels 7 and 8 (Fig. 6a). In the embodiment depicted here, the main stent is then deployed into position by inflation of the balloon 24 (Fig. 6b). During insertion and prior to dilation of the branch stent, the branch stent 15 is disposed around the distal end

of a branch catheter 54 which may optionally include an inflatable balloon 25, and the contacting portion 18 of the branch stent 15 is held in a collapsed position by a protective sheath 34, as shown in Fig. 6c.

In the bifurcating double-stent apparatus 10 of the invention, once the main stent 12 is dilated and the stabilizing catheter 44 (as shown in Fig. 6b) is removed, the branch stent 15 is inserted over the branch guidewire 36 and through the opening 16 of the main stent 12 substantially as shown in Fig. 6c, and affixed in place by withdrawal of the protective sheath 34 (Fig. 6d) and insertion of the branch stent 15 until it at least partially contacts the perimeter of the opening 16 of the main stent 12 by the expansion of the contacting portions 18 which are positioned at the proximal end 30 of the expandable stent, as shown in Fig. 6e. The branch stent 15, once positioned in the branch vessel 7, may be then fully expanded by the balloon 25, as shown in Fig. 6f. The angle at which the optionally expandable branch stent 15 is affixed depends upon the vessel structure into which the bifurcating stent apparatus 10 is inserted. All catheters and guidewires are then withdrawn from the subject vessels, leaving the main stent 12 through which the branch stent 15 is inserted into the branch vessel 7, forming a bifurcated stent 10 (Fig. 6g).

As illustrated in Figs. 6a-6g, the main stent 12 is deployed prior to the branch stent 15. This is the presently preferred order of deployment. It will be possible, however, in some circumstances to deliver the branch stent 15 prior to the main stent 12. In such cases, the branch stent 15 will be deployed with the contacting portions 18 opened directly against the inner wall of the main blood vessel. The main stent 12 will then be positioned over the contacting portions 18 of the branch stent 15 and firmly expanded thereagainst. A sheath or expansion balloon can be used to properly align the side opening 16 of the main stent 12 with the opening within the contacting portion 18 of the branch stent 15.

In the embodiment shown in Figs. 7-9, the main stent 40 with expandable portion 38 is positioned within the vessel 8 by the guidewires 20 (Fig. 7), and affixed in place by radial expansion of the main stent 40, most particularly by inflation of the balloon 25 (Fig. 8). The main stent is positioned so that the opening 16 is directly over the bifurcation point 50 in the subject vessels 7 and 8 (Fig. 7 and 8). In order to aid such positioning, a side branch guidewire 36 and a stabilizing catheter 44 (as depicted in

Fig. 7) are also inserted through the opening 16 of the main stent 40 and through the expandable portion 38 and into the branch vessel 7 (Fig. 8).

The optional expandable portion 38 of the main stent 40 is then expanded radially and in an at least partially perpendicular manner to the sides of the main stent side opening 16 (Fig. 8). In the embodiment illustrated in Figs. 7 and 8, a balloon 25 is deployed along the side branch guidewire 36 through the expandable portion 38, and inflated until the expandable portion is fully expanded into the branch vessel 7 to cover the bifurcation point 50 of the branched vessel, as illustrated in Fig. 8. In order to extend the expandable portion 38 into the branch vessel 7, a balloon 25 disposed around a branch catheter 54 which is threaded along the side branch guidewire 36, through the main stent 40, through the opening 16 and expandable portion 38, and into the subject branch vessel 7 as shown in Fig. 8. The expandable portion 38 is then extended into the branch vessel 7 by inflation of the balloon 25, which pushes the expandable portion 38 outward radially and lateral to the side opening, into the branch vessel 7 (Fig. 8). Once all catheters and balloons are withdrawn, the expandable portion 38 is arrayed in lateral orientation to the sides of the opening 16 in the main stent 40, and surrounding the opening 16 into the vessel branch (Fig. 9). The guidewires 20 and 36 are then withdrawn from the main and branch vessels.

The expandable portion 38 is illustrated as a plurality of elements which are attached to the peripheral edge of the side opening 16. The elements project radially inwardly into the side opening and thus lie within the cylindrical envelope of the tubular main stent 40 prior to deployment, as shown in Fig. 7. The elements are opened by outward lateral deflection, typically using a balloon catheter, as illustrated in Fig. 8. The deflected elements both traverse the transition between the stent and the lumen of the branch vessel and also serve as an anchor for subsequent placement of the second stent.

In the double stent apparatus of Fig. 5 and in the main stent with expandable portion illustrated in Figs. 7 and 9, the main stent as well as the expandable portions may be constructed at least partially of and/or coated or plated with an imageable material or marked with imageable markers 56 at suitable locations, including around the perimeter of the side openings of the main stent and at the ends of the expandable portions. In the differentially expandable stent structures of Figs. 10-12 (described below), a distal portion may be radiopaque with the remainder being radiolucent. Suitable imageable materials are radiopaque, such as gold, tungsten, and the like.

When reinforcing a bifurcated vessel where both branches of the vessel require reinforcing, either 1) the single main stent with the expandable portion is used whereby the expandable portion extends into the vessel branch at least partly covering the origin of the bifurcation, which may be used alone or in combination with any conventional stent; or 2) the main stent without the expandable portion and at least one branch stent with contacting portion are used, the branch stent placed to extend through at least one side opening of the main stent into at least one branch vessel, wherein the branch stent is at least partially in registry and contacting the edge of the side opening through which it extends. The branch stent extends laterally at varying angles to the side opening of the main stent. When treating a bifurcated vessel where the area to he treated spans the bifurcation and unobstructed access to the unstented vessel is required, the main stent may be used either with or without the expandable portion, wherein at least one side opening is placed over the bifurcation point.

The stent apparatus of the invention may be constructed from any non-immunoreactive material, including but not limited to any of the materials disclosed in the prior art stents which are incorporated herein by reference. It is intended that the stent apparatuses of the invention may further be at least partially constructed of, or marked at certain points with, a material which may be imaged, most particularly but not limited to by x-ray and ultrasound.

The stents of the invention may be deployed according to known methods utilizing guidewires and catheters, which are then withdrawn from the subject following deployment of the stents. The subject stents may be self-expanding to conform to the shape of the vessel in which they are deployed, or they may be expanded utilizing balloon catheters, or by any other method currently known or developed in the future which is effective for expanding the stents of the invention. It is contemplated that prior to deployment the stents will be in a collapsed state, and will require either mechanical expansion (such as, for example, by balloon expansion) upon deployment or, for self-expanding stents, will require that the stent be confined to the catheter until deployment by, for instance, a retractable sheath, in which the sheath is removed during deployment and the stent self-dilated. The stents of the invention and the optional expandable portion of the main stent of the invention expand radially from their longitudinal axis, lateral to the side opening of the main stent. Other methods of dilation of the stents of the

invention may exist, or may become available in the future, and such methods are contemplated as being within the scope of this invention.

Referring now to Figs. 10-12, the present invention further provides stent structures having differential radial expansion characteristics. In particular, tubular stent structures having side holes, generally as described above, are configured so that a portion of the stent on one side of the side hole will expand at a different yield or threshold force than a portion of the stent on the other side of the side hole. Such different yield forces or pressures may be achieved in a variety of ways. For example, referring to Fig. 10, a stent 100 is illustrated in a "rolled out" view, i.e., the tubular stent is broken along an axial line and then rolled out in the resulting pattern shown in the Figure. The pattern shown in Fig. 10 is prior to expansion. The stent 100 includes a side hole 102 defined by a continuous band 104 having a plurality of loops 106 projecting into the open interior of the side hole. The loops 106 are an integral part of the band 104 and will, prior to expansion or opening, lie within the cylindrical envelope of the tubular body of the stent. The first portion 110 of the stent lies on one side of the side hole 102 and is defined by a plurality of serpentine rings 112. The serpentine rings are joined by axial expansion spring structures 114 so that the stent may be bent as it is introduced and/or deployed. A second portion 120 of the stent 100 is formed on the other side of side hole 102. The second portion is also defined by the plurality of serpentine rings 122 which are generally similar in structure to the rings 112 of the first portion 110. Each of the portions 110 and 120, however, include an axial spine 130 and 132. The axial spine 130 of the first portion 110 comprises simple W-shaped structures including outermost struts 134 which open at a relatively low expansion force on the adjoining hinge regions. In contrast, the axial spine 132 of the second portion 120 comprises box elements 138 which require a greater expansion force to open. Thus, in deployment, the first portion 110 will yield first to allow partial opening before the second portion 120 begins to open.

A second stent structure 200 having differential expansion characteristics is illustrated in Fig. 11. A side hole 202 is formed from a continuous band of material, generally as described for Fig. 10. A first portion 204 and second portion 206 of the stent each comprise a plurality of serpentine ring structures 208 and 210, respectively. While the specific geometries differ, the structures of stents 100 and 200 are generally the same, except for axial spine portions 220 and 230 in the first portion 204 and second portion 206, respectively. The first spine portion 220 comprises a simple U-shaped loop

having a pair of struts joined by a simple C-shaped hinge region. The spine 220 will thus open at relatively low expansion forces. In contrast, the axial spine 230 of the second portion 206 comprises a serpentine element which allows for axial expansion but does not permit radial expansion at all. Thus, the first portion 204 will begin opening at much lower expansion forces or pressures than will the second portion 206.

A third concept for providing differential expansion is illustrated in Fig. 12. Stent 300 comprises a side hole 302 (which is shown in halves in the illustration), a first portion 304, and a second portion 306. The first portion 304 and second portion 306 each comprise serpentine rings 308 and 310, respectively. Differential expansion, however, is not achieved by providing a particular axial spine region, but rather by having different characteristics in the serpentine rings 308 and 310. The serpentine rings 308 have axially aligned struts joined by simple hinge regions. The length of the struts is relatively long (compared to those in the second portion 306 as described below) so that the rings will open at a lower expansion pressure or force. The serpentine rings 310 of the second portion 306 have relatively short axial struts defined by hinge regions each having two bands. Such structures require a greater expansion force than do the serpentine rings 308 of the first portion.

It will be appreciated that numerous other specific designs may be provided for differential expansion. What is important to the present invention, however, is that at least a portion of the stent on one side of the side hole, usually the entire length of the stent on that side of the hole, will be able to open prior to opening of the stent on the other side of the side hole. Preferably, the first portion of the stent will open at a balloon expansion pressure in the range from 1 atmospheres to 10 atmospheres, while the second portion of the stent will open in response to a balloon expansion pressure in the range from 2 atmospheres to 18 atmospheres.

Referring now to Figs. 13A-13H, deployment of stent 100 will be described. While reference is made to stent 100, it will appreciated that the same method could be used as well with either of stents 200 or 300. Initially, a pair of guidewires GW1 and GW2 will be deployed in the lumen, typically a bifurcated blood vessel, so that guidewire GW1 extends through the main lumen of the main vessel past the ostium O of the branch vessel BRV. The second guidewire GW2 will be advanced through the lumen of the main vessel and into the lumen of the branch vessel BRV, as illustrated in Fig. 13A. The stent 100 will then be introduced over the guidewires on a delivery

catheter 400 having an expansion balloon 402, where the stent is crimped over the expansion balloon. A sheath 404 is disposed in the second portion 120 of the stent with its distal tip (not shown) terminating immediately before the side opening 102. The assembly of the stent 100, delivery catheter 400, and sheath 404 will be delivered with the first guidewire GW1 passing through a guidewire lumen of catheter 400 and the second guidewire GW2 passing through the sheath 404, as illustrated in Fig. 13B. Initial alignment of the side hole 102 of stent 100 is achieved by advancing the stent so that the side hole lies close to the ostium O.

After an initial rough alignment is achieved, the balloon 402 is inflated to an initial inflation pressure which opens the first portion 110 but which leaves the second portion 120 in its substantially unexpanded configuration, as shown in Fig. 13C. Such partial opening allows the sheath 404 to be advanced over guidewire GW2 to better align the side hole with the branch vessel BRV, as shown in Fig. 13D. The sheath provides much greater stiffness than the guidewire, permitting manipulation of the partially deployed stent 100 to achieve the better alignment.

Referring now to Fig. 13E, after alignment is achieved, the balloon 402 will be inflated to a greater inflation pressure to open the second portion 120 of the stent 100 as well. A balloon catheter can then be advanced over the second guidewire GW2 so that balloon 502 can be expanded within the side opening 102 to open the loops 106, as illustrated in Fig. 13F. In many cases, this will be sufficient deployment for the stent where the loops provide the necessary anchoring and transition at the ostium O.

Optionally, a secondary stent 600 may be introduced as illustrated in Figs. 13G and 13H. The stent 600 is introduced over a balloon 702 on balloon catheter 700. The final deployment configuration is illustrated in Fig. 13H.

It is intended that the invention include all modifications and alterations from the disclosed embodiments that fall within the scope of the claims of the invention.

WHAT IS CLAIMED IS:

1. A stent for placement in a bifurcated body lumen having a main branch and a side branch, said stent comprising:

a main tubular stent body having a first end, a second end, a lumen therethrough, and a side opening have a plurality of laterally deployable elements therein.

2. A stent as in claim 1, wherein the elements are formed as an integral part of the stent body.

3. A stent as in claim 2, wherein, prior to deployment, the laterally deployable elements are aligned in a tubular envelope defined by the tubular stent body.

4. A stent as in any of the preceding claims, wherein the main tubular stent body is resilient so that it may be released from constraint for deployment.

5. A stent as in any of the preceding claims, wherein the main tubular stent body is deformable so that it may be expanded by a balloon catheter.

6. A stent as in any of the preceding claims, wherein at least a portion of the main stent body is radiopaque.

7. A stent as in claim 6, wherein at least a portion of the main stent body surrounding the side hole is radiopaque.

8. A stent as in any of the preceding claims, having a radially compressed configuration, wherein the length is less than 4 cm and the diameter is less than 2 cm.

9. A stent as in any of the preceding claims, wherein the side hole comprises a continuous band.

10. A stent as in claim 9, wherein the laterally deployable elements are inwardly projecting loops of the continuous band.

11. A stent for placement in a bifurcated body lumen, said stent comprising:

a main tubular body having a first end, a second end, and a side opening between said ends, wherein a first portion of the main tubular body between the first end and the side hole opens in response to a first radially outward pressure and a second portion of the main tubular body between the side hole and the second end opens in response to a second pressure, wherein the first pressure is less than the second pressure.

12. A stent as in claim 11, wherein the first pressure is in the range from 1 atmospheres to 10 atmospheres and the second pressure is in the range from 2 atmospheres to 18 atmospheres.

13. A stent as in claim 11 or 12, wherein the first portion has a first axial spine and the second portion has a second axial spine, wherein the first axial spine opens circumferentially to a first force and the second axial spine opens circumferentially in response to a second force, wherein the first force is less than the second force.

14. A stent as in claim 11 or 12, wherein the first portion comprises serpentine rings with a first strut length and the second portion comprises serpentine rings with a second strut length, wherein the first strut length is greater than the second strut length.

15. A stent system comprising:

(a) a stent as in any of the preceding claims; and

(b) a second stent adapted to fit within and contact the laterally deployable elements of the main tubular stent.

16. A method for attaching a second stent to a first stent, said method comprising:

expanding a main tubular stent body; and

laterally deflecting a plurality of elements disposed about a side opening on the main tubular stent body.

17. A method as in claim 16, further comprising placing a second stent into the side hole so that said second stent engages the laterally deflected element.

18. A method for deploying a stent in a bifurcated body lumen, said method comprising:

providing a stent having a first portion, a second portion, and a side hole between said portions;

expanding a first portion against a luminal wall segment on one side of the bifurcation;

aligning the side hole with the branch lumen; and

expanding the second portion on the other side of the bifurcation.

19. A kit comprising:

a stent as in any of claims 1 to 10; and

instructions for use setting forth a method including the following steps:

(a) expanding the main tubular stent body in a body lumen so that a side hole on the stent body is aligned with a branching body lumen; and

(b) laterally deflecting a plurality of elements disposed about the side opening so that they enter into the branching body lumen.

20. A kit comprising:

a stent system in claim 9; and

instructions for use setting forth a method including the following steps:

(a) expanding the main tubular stent body in a body lumen so that a side hole on the stent body is aligned with a branching body lumen;

(b) laterally deflecting a plurality of elements disposed about the side opening so that they enter into the branching body lumen; and

(c) placing the second stent into the side hole so that said second stent engages the laterally deflected plurality of elements.

21. A kit comprising:

a stent as in any of claims 11-14; and

instructions for use setting forth a method comprising the following steps:

(a) expanding a first portion against a luminal wall segment on one side of the bifurcation;

(b) aligning the side hole with the branch lumen; and

(c) expanding the second portion on the other side of the bifurcation.

Fig. 1

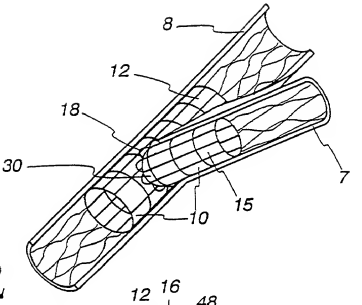


Fig. 2

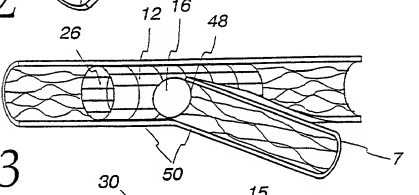


Fig. 3

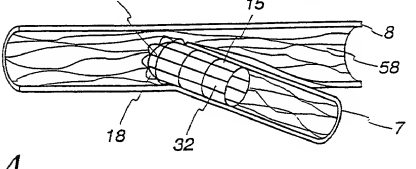
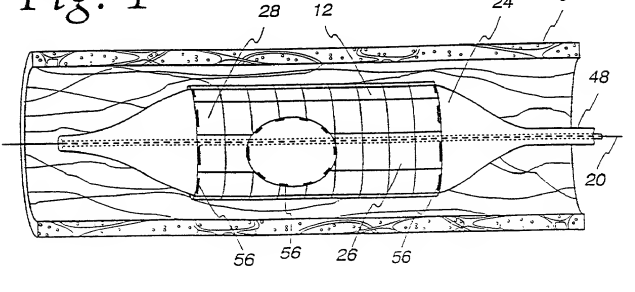


Fig. 4



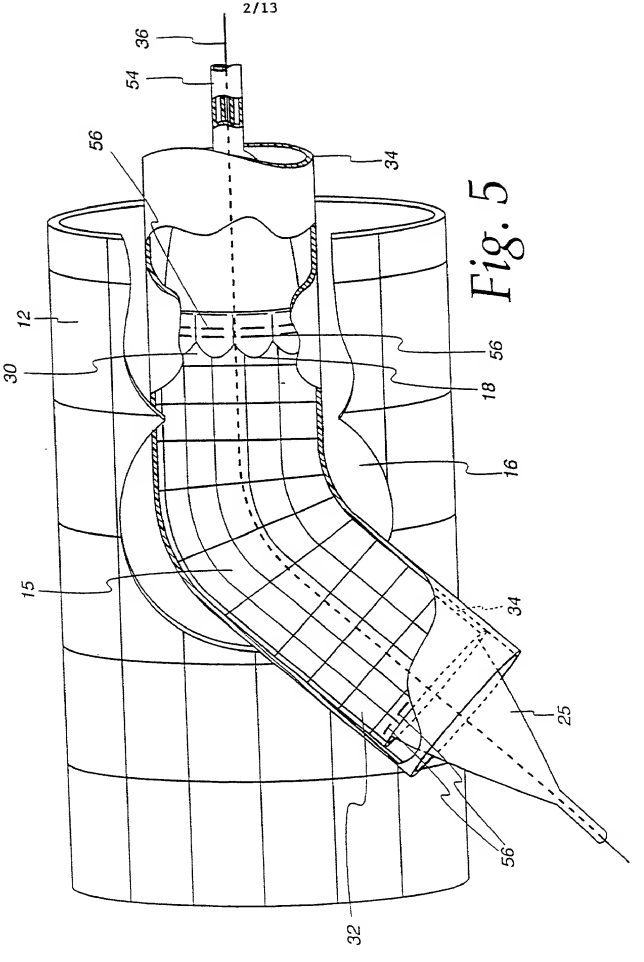


Fig. 5

Fig. 6a

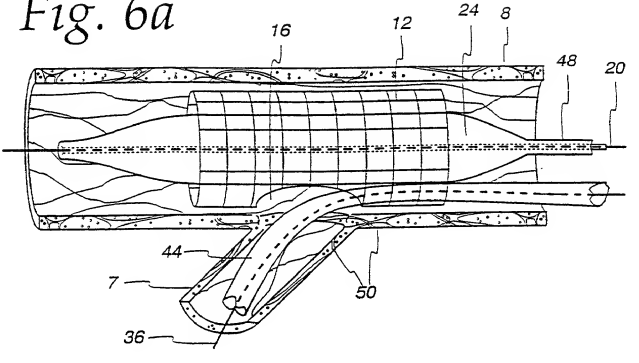


Fig. 6b

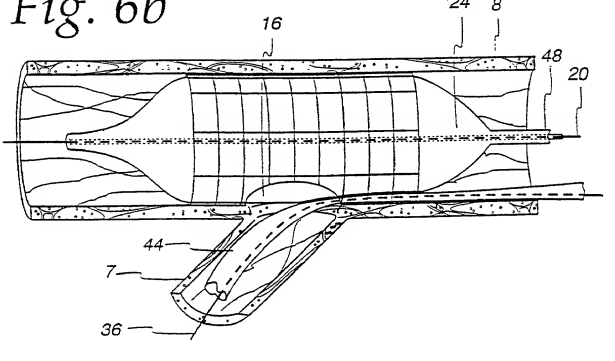


Fig. 6c

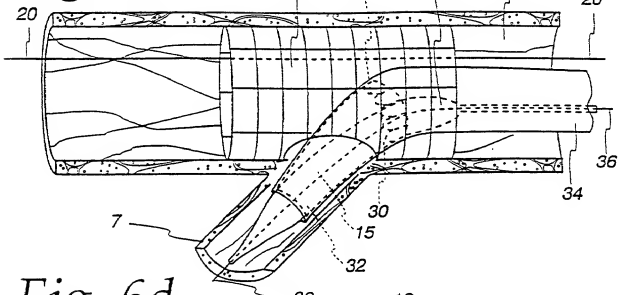


Fig. 6d

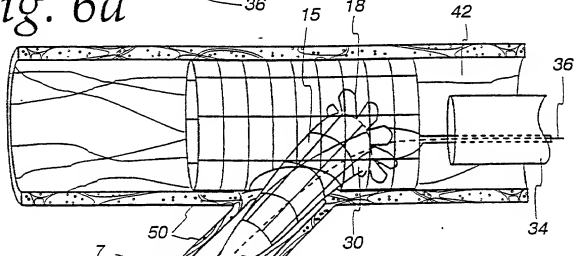


Fig. 6e

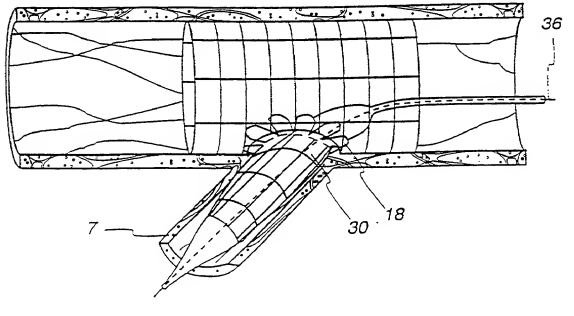


Fig. 6f

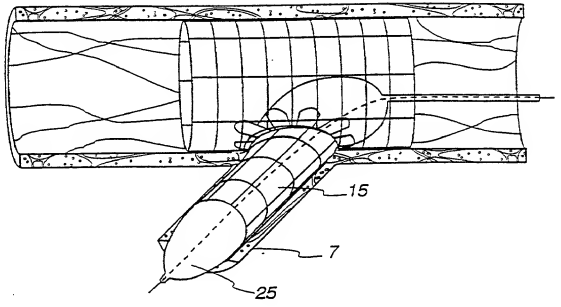


Fig. 6g

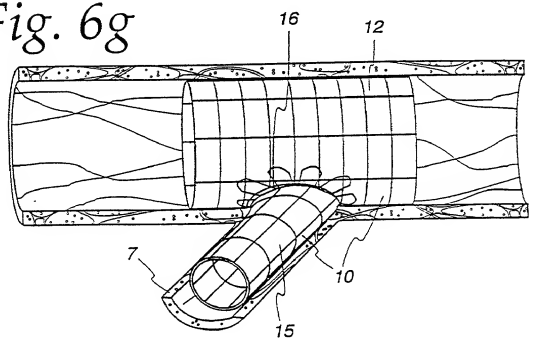


Fig. 7

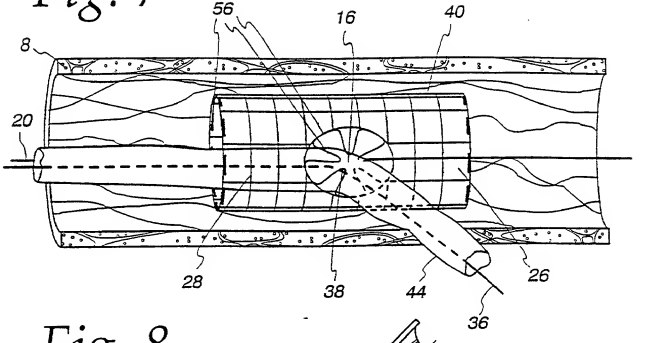


Fig. 8

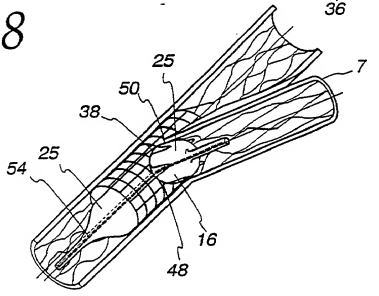
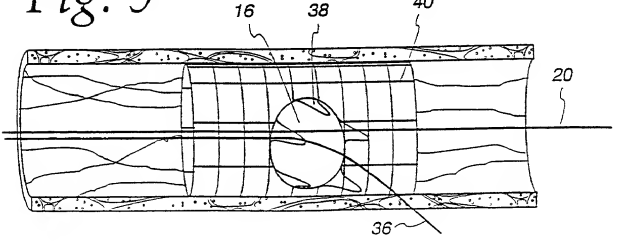


Fig. 9



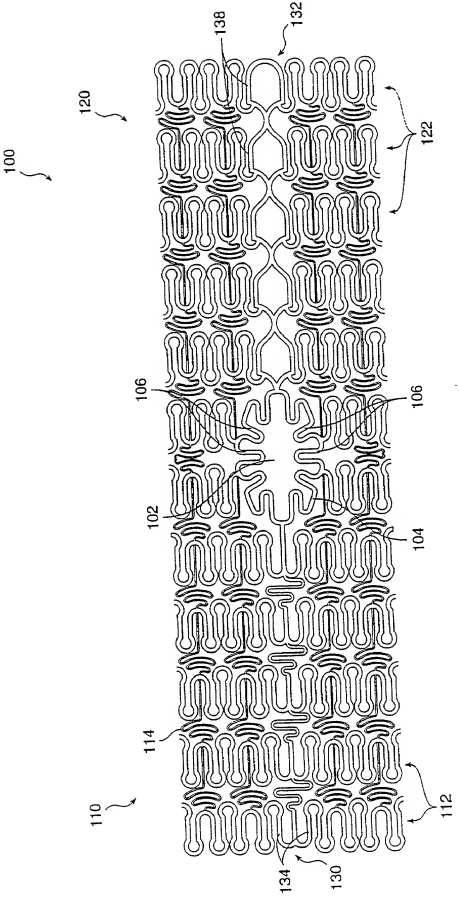


FIG. 10

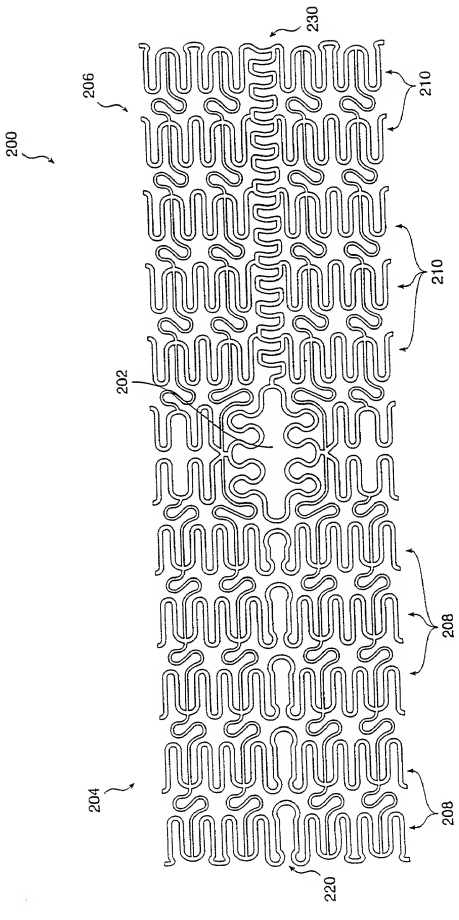


FIG. 11

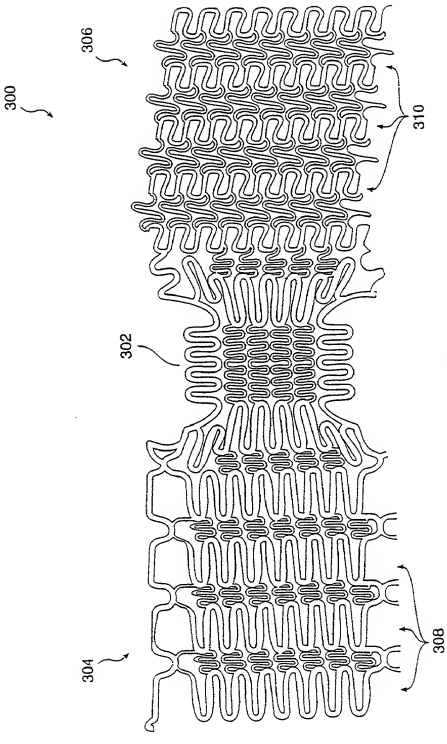


FIG. 12

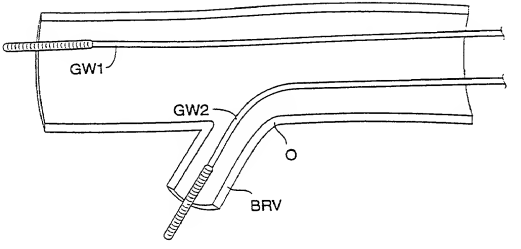


FIG. 13A

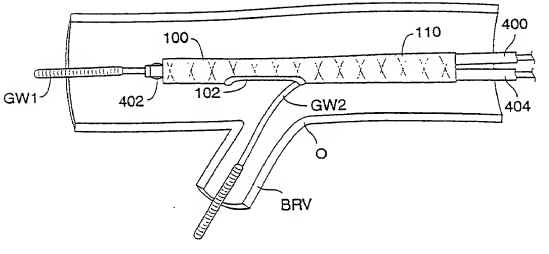


FIG. 13B

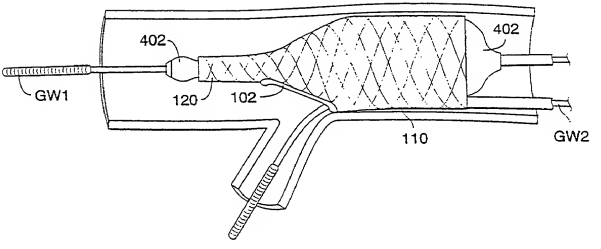


FIG. 13C

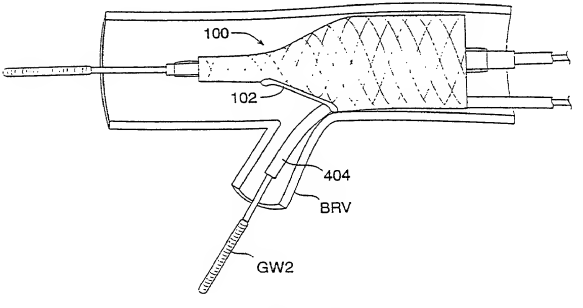


FIG. 13D

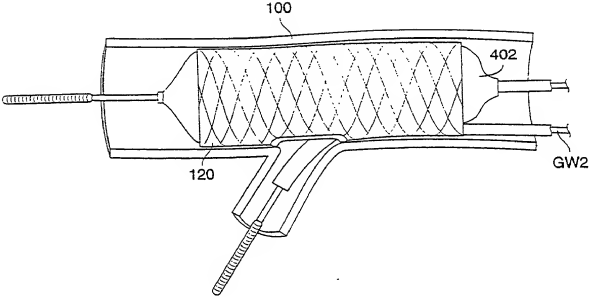


FIG. 13E

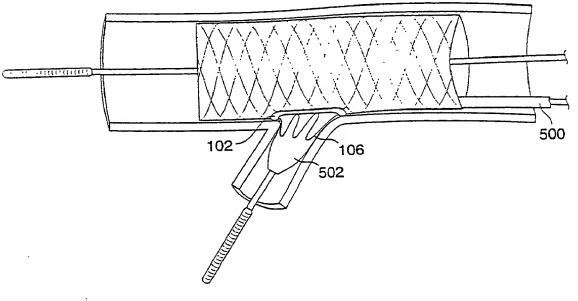


FIG. 13F

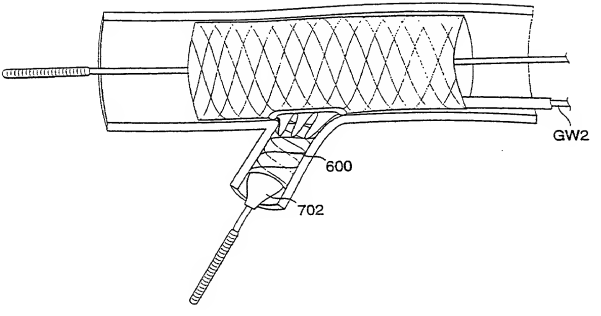


FIG. 13G

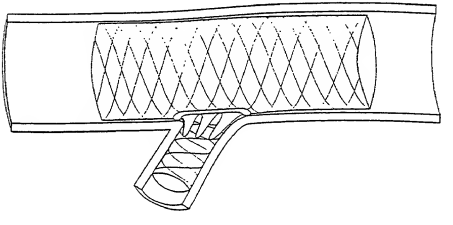


FIG. 13H

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	019601-000120US
First Named Inventor	Gil M. Vardi
COMPLETE IF KNOWN	
Application Number	09 / 600,348
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

EXTENDIBLE STENT APPARATUS

(Title of the invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) January 13, 1999 as United States Application Number or PCT International Application Number PCT/US9900835 and was amended on (MM/DD/YYYY) ____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

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Application Number(s)	Filing Date (MM/DD/YYYY)

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DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet
Page 1 of 1

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor							
Given Name (first and middle [if any])	Family Name or Surname							
Charles J.	Davidson							
Inventor's Signature						Date		
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Post Office Address	1311 Sunview Lane							
Post Office Address								
City	Winnetka	State	IL	ZIP	60093	Country	US	

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor							
Given Name (first and middle [if any])	Family Name or Surname							
Eric	Elam							
Inventor's Signature						Date	11/30/01	
Residence: City	Evanston	State	IL	Country	US	Citizenship	US	
Post Office Address	1125 Davis Street, #B3							
Post Office Address								
City	Evanston	State	IL	ZIP	60201	Country	US	

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor							
Given Name (first and middle [if any])	Family Name or Surname							
Stuart	Lin							
Inventor's Signature						Date		
Residence: City	Seabrook	State	TX	Country	US	Citizenship	US	
Post Office Address	2800 Nasa Road One #1307							
Post Office Address								
City	Seabrook	State	TX	ZIP	77586	Country	US	

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DECLARATION — Utility or Design Patent Application

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U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)
08/744,002	11/4/96	
09/007,265	1/14/98	

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As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☐ Customer Number → Place Customer Number Bar Code Label here
OR
XXX Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Lesley S. Craig	26,578		
Darin J. Gibby	38,464		
Roger T. Barrett	41,599		

☐ Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] OR ☐ Correspondence address below

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Address	Two Embarcadero Center, 8th Floor
Address	
City	San Francisco State CA ZIP 94111-3834
Country	United States Telephone (303) 571-4000 Fax (303) 571-4321

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Given Name (first and middle (if any))	Family Name or Surname
Gil M.	Vardi

Inventor's Signature								Date	
Residence: City	Chicago	State	IL	Country	US			Citizenship	US
Post Office Address	333 E. Ontario, Apt. 1002-B								
Post Office Address									
City	Chicago	State	IL	ZIP	60611	Country	US		

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(Title of the invention)

the specification of which
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OR
☒ was filed on (MM/DD/YYYY) January 13, 1999 as United States Application Number or PCT International Application Number PCT/US9900835 and was amended on (MM/DD/YYYY) [ ] (if applicable).

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			☐	☐	☐
			☐	☐	☐

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Supplemental Sheet
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Given Name (first and middle [if any])	Family Name or Surname
Charles J.	Davidson

Inventor's Signature	Charles J. Davidson					Date	10/26/00
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Post Office Address							
City	Winnetka	State	IL	ZIP	60093	Country	US

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle [if any])	Family Name or Surname
Eric	Elam

Inventor's Signature						Date	
Residence: City	Evanston	State	IL	Country	US	Citizenship	US
Post Office Address	1125 Davis Street, #B3						
Post Office Address							
City	Evanston	State	IL	ZIP	60201	Country	US

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle [if any])	Family Name or Surname
Stuart	Lin

Inventor's Signature	Stuart Lin					Date	
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Post Office Address	~~2800 Nasa Road One #1307~~ 937 CORONADO DRIVE						
Post Office Address							
City	~~Seabrook~~ COSTA MESA	State ~~TX~~ CA		ZIP	~~77586~~ 92626	Country	US

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Name	Registration Number	Name	Registration Number
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Darin J. Gibby	38,464		
Roger T. Barrett	41,599		

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Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] OR ☐ Correspondence address below

Name	Roger T. Barrett Townsend and Townsend and Crew LLP				
Address	Two Embarcadero Center, 8th Floor				
Address					
City	San Francisco	State	CA	ZIP	94111-3834
Country	United States	Telephone	(303) 571-4000	Fax	(303) 571-4321

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))	Family Name or Surname
Gil M.	Vardi

Inventor's Signature						Date	10/26/00
Residence: City	~~Town~~ County Chicago	State	~~IL~~ MO	Country	US	Citizenship	US
Post Office Address	~~333 E. Ontario, Apt. 1002-B~~	14203 STIFEL LANE COURT					
Post Office Address							
City	~~Town~~ County Chicago	State	~~IL~~ MO	ZIP	~~60611~~ 63017	Country	US

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